Search of FNS Q&A Testimony to Find 1 transcript...

On Tuesday, January 26, 1999
AND Selected from preview list

Senate Appropriations Cmte Hearing - Q&A: Harold Varmus, NIH, and Eric Meslin, Nat'l Bioethics Commission - Brain Stem Research [Transcript 990260161, 935 Lines]

HEARING OF THE LABOR, HEALTH AND HUMAN SERVICES AND EDUCATION
SUBCOMMITTEE OF THE SENATE APPROPRIATIONS COMMITTEE
SUBJECT: EMBRYONIC STEM CELL RESEARCH
CHAIRED BY: SENATOR ARLEN SPECTER (R-PA)
WITNESSES: HAROLD VARMUS, DIRECTOR,
NATIONAL INSTITUTES OF HEALTH
ERIC M. MESLIN, EXECUTIVE DIRECTOR,
NATIONAL BIOETHICS ADVISORY COMMISSION
138 DIRKSEN SENATE OFFICE BUILDING
WASHINGTON, DC
9:30 AM.
TUESDAY, JANUARY 26, 1999

SEN. ARLEN SPECTOR (R-PA): Morning ladies and gentlemen.

The Subcommittee on Labor, Health, Human Services and Education will proceed. We have scheduled this hearing on stem cells, which is the third in reasonably rapid succession, giving the hearing schedules of the subcommittee, this subcommittee or any subcommittee.

Because of the importance of stem cell research where there is such enormous potential for medical advances, the request has been made that the subcommittee not proceed to initiate legislation on the subject because that might complicate the use of stem cells under an opinion, which has just been rendered by legal counsel for the Department of Health and Human Services and we want to work with HHS and NIH to see to it that the most appropriate course is followed here.

The definition of organisms and stem cells and the entire medical lexicon is extraordinarily complicated. We have noted that NIH researchers will only be allowed to work on stem cells obtained by private sources. No NIH supported researchers will be allowed to conduct direct work on a human embryo, even to obtain stem cells consistent with the existing ban. That is an advance, but it's limited, obviously on the face, and there are a series of NIH caveats, in that NIH will not fund any human cell research until such time as special guidelines are developed, addressing relevant, ethical and moral issues. So that is a constraint and NIH plans to convene a special oversight group to review all research grant applications involving human stem cells in addition to regular scientific review process, which is another limitation.

And then NIH has asked the National Bioethics Advisory Board for additional guidance and I appreciate the thinking of NIH on all these very complex subjects and the hearing today will focus on to what extent that may delay the research. And there's a question as to whether additional legislation is needed, which we will be addressing and these are very, very difficult legal problems and that only begins to scratch the surface of the ethical problems, which underlie them. And the question is in my mind as to whether legislation is necessary or desirable. Maybe we shouldn't have any legislation.

My preliminary thinking is, as I expressed it in the second hearing, after studying the issue from our initial hearing, was that we really ought to utilize this kind of research and if it requires legislative change, then I think we ought to proceed in a expeditious way, but in a careful way. So Dr. Varmus, that's a very, very brief outline of some of the problems running through my thinking on it.

We welcome you here, again, today. I know that there's scheduling problems among the panel and there is a scheduling problem with the subcommittee. We've advanced the hearing, as you know, to 9:00 because we have a caucus on the impeachment case, which is a very time consuming, but it is my firm view that we ought to be taking care of other problems as well. So whatever time we have to meet to do that or however we can proceed in an appropriate, but expedited fashion, we intend to do that. And I know you're experienced at it, Dr. Varmus.

So we thank you for coming. We compliment you again on the outstanding work you have done at NIH over the years and we have put the government's money where our praise is to paraphrase a famous statement.

The floor is yours, Dr. Varmus.

DR. HAROLD VARMUS: Mr. Chairman, thank you very much.

SEN. SPECTOR: I'd like you to limit the opening statements to five minutes to leave maximum time for questions.

DR. VARMUS: I appreciate your attention to these issues, despite your complex conflicting demands on your time.

Our purpose today is threefold. I'm going to just say a couple of words to remind you about the scientific prospects here, review the legal decision that you've alluded to and outline the next steps the NI proposes to take to pursue our intention to support research with these new stem cells. I'll remind you that human pluripotent stem cells were recently isolated by two methods. First, from fetal tissue after an elective abortion and from embryos that were donated after successful treatment of infertility. Neither of these events were supported with federal funding.

Now, human pluripotent stem cells can divide and culture for long periods. That's part of their usefulness -- good morning, Senator -- and have the potential to form virtually any kind of tissue. The research application of these cells are various and important. They include attempts to understand human development, efforts to develop drugs and tests for drug toxicity in new ways and the potential for developing cell therapies for many diseases, injuries and conditions.

We discussed in December, at your hearings, the issue of federal support for this science and, indeed, other kinds of science as well. And as you heard from the panelists, at that time, there are several advantages to receiving federal support in this area, the open exchange and the more intense and accountable oversight, the greater number of dollars and the more talent recruited to these problems and the ultimate, faster progress toward public health goals.

We at the NIH respect and recognize many ethical and legal concerns about human pluripotent stem cells and the modes by which they are derived. And we are firm in our conviction that federal funds should not be used for this purpose until both the legal concerns and these ethical concerns have been addressed and many constituencies, including Congress and the public have been consulted. As a first step, I asked the general counsel, Harriet Rabb, who's sitting with me today, for a legal opinion about the federal funding of research with these cells, distinguishing carefully between the use of the cells and their derivation. In other words, can we support work with the established human pluripotent stem cells in view of the appropriation law that you alluded to that bans the use of federal funds for embryo research?

The essence of her opinion, which you have been given, is that first, yes, we can fund work with human pluripotent stem cells derived from non-living fetuses under the existing statutes that govern fetal tissue research. Secondly, we can fund work with human pluripotent

stem cells that are derived from embryos because the cells themselves are not organisms. They cannot become organisms and hence they are not embryos as defined by law and indeed, at your December hearing, prompted by Senator Harkin, all witnesses agreed with this definition.

Now under the appropriation law, it's also the case that we cannot use these stem cells to make an embryo, for example, by somatic cell nuclear transfer and of course we cannot fund work to derive such cells from embryos, although we can do so from fetal tissue. Now I presented these views at a meeting of the National Biologic Advisory Commission on January 19th. That meeting was held on this topic in response to a presidential request that the entire area of stem cell research be reviewed in view of the promises of recent work because he felt that recent advances had indicated that there was a need to reassess the balance between the ethical concerns about such work and the promise for medical research. We welcomed the review by NBAC. We specifically seek prompt guidance with respect to the ethical considerations that will allow us to carry out appropriate oversight on this research.

But what are our next steps? Well first, as I've made clear on many occasions, no immediate funding is occurring until we have our guidelines and process in place. This has been communicated to all of our investigators, both intramurally and extramurally through memos and Internet postings and news reports. Secondly, I am establishing a subcommittee of my advisory committee to the director, which has ad hoc members from all the relevant specialties. That subcommittee will work with NIH staff to compose guidelines for the conduct of research on these cells. The guidelines will address the work to be done with the cells, how the cells were derived and how the starting materials were obtained.

There are important frameworks that will make this formulation of guidelines easier. There are federal rules for work with fetal tissue that will be helpful and some years ago, in 1994, a human embryo research panel issued recommendations that were extremely thoughtful and will be important guides in the development of guidelines. Finally, the group will also be consulting with the NBAC, with Congress, with the public. We will be publishing a draft of our guidelines in the Federal Register for comment. We expect to have the guidelines written and presented to the public in the course of the next couple of months.

We will then promulgate those guidelines and then in a manner to be determined by the working subcommittee and oversight group we'll ensure that all who do this work are actually in compliance with the guidelines.

We expect that the vast majority of applications will be mostly routine, that is, they will be applications to work with the existing cells that have been described and whose providence is well understood.

Any uncertainties will be referred to further public discussion, and we will carry out annual reporting to Congress and the public about the status of the science, the number of investigators and any change proposed for the guidelines. Now, before I conclude these remarks, let me just make a personal comment, that since I made my presentation to NBAC last week, my staff and I have received many, many thoughtful, interesting, perplexing questions. Let me just address two of those that I think will help inform our discussion.

First, we've been asked, isn't working with these stem cells like using stolen goods, because some of them are derived from embryos and that embryo research is forbidden. No, no. It is not illegal to derive human pluripotent stem cells. What is forbidden is the use of federal funds to derive them from embryos. In this sense, it's like many legal activities which federal funding is not permitted. No federal funds were used, no laws were broken in producing these stem cells, and we have determined that no laws would be broken if federal funds are used to support work with them, once they have been derived.

The second question we frequently hear is, won't federal funding for human pluripotent stem cells create a demand to create additional human embryos? Again, the answer is no. There are thousands of embryos, indeed, probably tens of thousands of embryos that are frozen and discarded in US in vitro fertilization clinics each year, because they are in excess of the number required from successful treatment of infertility. In contrast, human pluripotent stem cells derived from very few embryos can be used by many investigators for hundreds of experiments because it's usually possible to keep these cells growing for many generations, as for many cell doublings.

Furthermore, federal guidelines that protect against coercion and the procurement of fetal tissue are likely to be emulated in the construction of our guidelines for work with human pluripotent stem cells. Mr. Chairman, no doubt you and Senator Harkin have other questions. I'd be pleased to answer them now.

Thank you very much.

SEN. SPECTER: Thank you very much, Dr. Varmus.

Before yielding to my distinguished colleague, we're going to turn to Dr. Rabb. We appreciate your being here, Dr. Rabb. You served as general counsel for the Department of Health and Human Services since May of 1993, very substantial tenure, former director of the clinical education of Columbia Law School, vice-dean of the Law Faculty in 1992. We appreciate your joining us and the floor is yours, Dr. Rabb.

DR. HARRIET RABB: Thank you.

Thank you, Senator. I wanted to spend the time today answering your questions, if I may. You have my legal opinion. It is available to you for any questioning you'd like to put to us, and I thought we should save the time, if you don't mind for that.

SEN. SPECTER: You're waiving your opening statement?

DR. RABB: If you don't mind.

SEN. SPECTER: Okay.

Let me turn at this point to my distinguished colleague, Senator Harkin.

SEN. TOM HARKIN (D-IA): Thank you, Mr. Chairman. And again, thanks for holding this follow up hearing. This is an area that has captured my imagination, and I think it's one of the most exciting new realms that we have in science that just holds so much promise. And that's why I'm just delighted that we got your decision, Dr. Rabb on this that this research could feed the pace. I congratulate you, Dr. Varmus on setting up the subcommittee and do this in a careful procedural, open way so that the public is aware of what we're doing.

There is, as you know, a lot of concern about this and there are ethical considerations, I don't downplay those at all. As I've said before on many occasions that I believe that science, especially in this area, in stem cell research holds so much promise for alleviating human suffering and debilitating disease that we have to move ahead aggressively.

Although, I have said that we have to be careful about the ethical considerations, I believe that scientists working with ethicists and lawmakers together, getting good public input, I believe we can craft that. I believe we have and I believe you have, doctor. And I think you have a great structure. As I understand it your guidelines going to be out in a couple of months. That was the first question that I had, but you answered it. In a couple of months you have these guidelines ready to go. And I assume then that funding could then proceed after that, I would hope.

DR. VARMUS: We will. We will submit for public comment, for 30 days public comment.

SEN. HARKIN: I see, so I'm just wondering do you have any idea right now -- I'm certain requests must be coming in even as we sit here.

DR. VARMUS: Correct.

SEN. HARKIN: What sort of backlog do you see out there of requests coming in for this king of funding?

DR. VARMUS: Well, I have only indirect information. There will be three ways at least to support this research. Some investigators already have grants and they may be working in this general area, but want to shift their emphasis to work with human stem cells. There will be others who may want to supplement existing grants by a small research application. And others want maybe want to initiate a new grant.

In addition, we have intramural investigators who maybe interested. The only way we have to gauge the level of interest at this point is to ask Doctors Thompson and Gearhart who have made these cell lines, how many requests they've received? And we know they've received in the order of 50 to 100 requests from various investigators for these cells to be worked with. But the investigators have been informed that at this point NI's funding is not to be used until we have our procedures in place. And we hope, as I say, that that will be within the next few months.

SEN. HARKIN: Well, I appreciate that. And again I am grateful for your opening statement in terms of addressing head on this issue of encouraging the creation of embryos. I've heard a lot about that. But as you point out, because of in vitro fertilization we have a lot of those who are out there, plus the fact that these very potent cells can continue on. And so, I don't think there's any problem there at all. And I'm happy that you addressed that issue. I guess the rest of that question, I just encourage you, Dr. Varmus. I don't think you need any encouragement in this area, but to really push ahead. I mean, the more reading I do on this, I'm not a scientist, but the more reading I just -- this holds so much promise. And it could be in not too long a time for people suffering from --(coughing) -- or heart disease just understanding cancer cell biology, for example, things like that that we just haven't had that grasp on right now.

I just, again, hope that you'll foresee the pace, again, keeping in mind the guidelines and the need for public input and open ethical guidelines. All that taken into account I just hope that you will do everything you can to get the funding out to the researchers. If we need to do anything here in the subcommittee, I know Senator Specter has gotten us a whole lot more money to put into the medical research this year, so if you need any more of that money we can maybe help out. I'm just kidding,-- (laughter) -- putting you in a tough spot. But I hope that we can get that. We're working together on that. I think the budget from the administration is going to be willfully inadequate to meet the needs that we have out there. And I'm hopeful that we can get more. So, any information that you have on the need for this, in terms of our responsibilities here for funding, I encourage you to let us know as soon as possible.

DR. VARMUS: I'll do that Senator. Thank you.

SEN. HARKIN: Thank you, Doctor.

SEN. SPECTER: Thank you, Dr. Rabb, for --

DR. RABB: Thank you.

SEN. SPECTER: -- your (contribution and your time?).

Dr. Varmus, I'll begin with a baseline question. Just what is the extent of the potential in your professional opinion, from the stem cells. We've heard very extraordinary comments about potential on Alzheimer's and Parkinson's and diabetes and cancer and heart ailments and the whole range of human medical problems. You're the great expert, director of NIH. Is that potential accurately stated?

DR. VARMUS: Well, no doubt as in all realms of discussions of this topic, there may be some hyperbole, but much of it is, in my view, accurate. We have experience with similar work done in experimental animals. For example, in mice. And we know that it's possible, we had a long experience, now, nearly 18 years or so, working with the parallel types of cells. Pluripotent stem cells for mice. And we know that those cells can be induced to differentiate into certain kinds of cells. And those cells can be used to replenish diseased or impaired or missing cells in mouse models of disease, that the prospects for repairing damaged hearts and treating congestive

heart failure, for example, for returning, missing components of the blood system, are all very real.

There will be difficulties in treating more complex diseases like Alzheimer's. And I don't think we should minimize the challenge there. However, in conditions like diabetes, where we know one specific type of cell is missing, and that that cell produces a product which circulates in the body, I think the prospects are great. As I emphasized last time, there are two major impediments to using these cells in cell therapy. One is that we have a still very limited idea of how to take mass cultures of these cells and direct them efficiently into one cell lineage.

But that information will come as we study the way in which these cells undergo their changes in program that allows them to select a cell type to become.

The second problem is one of rejection, histo-compatibility (ph), the classic problem in transplantation. We know that those problems may be at different levels of severity with different tissues. We also know that there are ways to manipulate the cells in culture to make them seem less foreign to the host.

Furthermore, there are new methodologies that are in development that could obviate these problems in other ways. For example, by using our understanding of how cells work and their apparent plasticity to take one kind of cell from the patient himself or herself and to remodel that cell to make it able to replace a diseased or absent tissue.

SEN. HARKIN: Dr. Varmus, you say that diabetes, you single that out as one, which is closer to solution. I know form time to time we press you unduly as to a timeframe, maybe, not unduly, but we press you because for that is a very strong argument with our colleagues to get additional funding, if you can put it in a timeframe. Could you give us a ballpark figure as to say diabetes, when this research might produce the cure?

DR. VARMUS: Well, as you know, Senator, I tend to be more conservative than some of my colleagues, in making these predictions. But in the case of Type I diabetes, where we know that the replenishment of the beta cell of the auto-telangerhans (ph) to the pancreas does have an important positive effect in some patients who've been treated, for example, with pancreatic transplantation. In that setting where we know what we need to do, the major challenge is to figure out a way to make a pluripotent cell become a beta cell.

SEN. HARKIN: Can you give us a ballpark figure as to how long?

DR. VARMUS: I would say certainly no sooner than five years, but beyond that I'm guessing, but --

SEN. HARKIN: Let me ask you now about when these guidelines will be out, when you'll be able to start using funds for research? You have a whole series of preliminaries, the special guidelines, the oversight group, additional guidance from the National Bio-ethics Advisory Board. A comment period, when?

DR. VARMUS: All right.

SEN. HARKIN: I approach this question with the sense of urgency because, and I don't think it's hyperbolae to say that every day lost, human lives are lost. So, when?

DR. VARMUS: I share your concerns, Senator. It's been, but I do think it's important to have an open and fair process because of the many concerns that are felt. And the feeling that public and Congress want to have a chance to express their opinions. I'm currently assembling the group who will work with us to establish the guidelines.

In the case of the existing cell lines, the cell lines that have been made, reported, we know all the details about how the tissues were obtained, I think it's going to be very straightforward. We have a legal opinion. We have the human embryo, our research panel guidance. We have regulations with regard to fetal research that are

very useful. I believe that in the course of the next couple of months, a clear set of guidelines governing work on those cells can be generated.

I've asked Dr. Shapiro, the chairman of the National Biologic Advisory Commission if they would attempt to give us some preliminary information about this specific issue in the course of their larger evaluation of embryo research in general. I hope we'll have our guidelines out for public comment within a couple of months. There'll be a 30-day public comment period. At that point we can begin to allow our investigators to use federal funds.

SEN. SPECTER: So you say a couple of months to April 1st and a 30-day comment period and then that brings us to May 1st?

DR. VARMUS: Now I don't want to prejudge exactly how my advisory committee will do its work and I don't know exactly how they will segregate the different domains of research because they may find that some things are very cut and dried and we can move very quickly on; that other issues, for example, what to do in response to another set of cell lines -

SEN. SPECTER: Dr. Varmus, we understand you have the problems and we're pressing on the date so we can figure out the time parameters and we know how to respond. We don't want to schedule the next hearing prematurely. My red light is on.

Let me yield to Senator Harkin.

SEN. TOM HARKIN (D-IA): I just want to just follow up on one thing. It's been my experience, though, getting back to the timeframe and how things work out and when can we expect results. Twenty-three years I've served on committees in the House and Senate that deal with the National Science Foundation and now NIH. It's been my experience through those years that when you're dealing in basic research, well and this is sort of basic and applied, there's kind of a fuzzy boundary here in this one, that sometimes you put a timeframe but you know sometimes serendipitous things happen in science. But they won't happen unless you start moving down the pathway. So you can talk about five years or something, but you never know. I mean maybe in a year from now or something some scientist working someplace something happens and you come up with something and that's why I think it's so important to move ahead aggressively in this because like I say you never know. I just wanted to make that point that a lot of times in science those things just happen like that.

DR. VARMUS: Well I appreciate being castigated for my conservative position. I'm usually thought of as too impetuous so I appreciate your comments, Senator.

SEN. HARKIN: Thank you, Dr. Varmus.

SEN.SPECTER: We're going to ask you to stay with us Dr. Varmus and Dr. Rabb. I'd announced at the outset that there are caucuses at 10:00, at least the Republican caucus at 10:00, also with Senator Harkin on the caucus of the Democrat Senators.

We're going to move now to panel two. We're going to conclude the hearing by 10:00. And we have not gotten Dr. Rabb into the definitions, but we do have your very learned opinion. And if you'd stand by for some dialog and q and a, we'd like to call now Dr. Eric Meslin and Mr. Richard Doerflinger. Dr. Meslin is the executive director of the National Bio-ethics Advisory Commission. He received his Bachelor of Arts degree from York University, Toronto, MA and Ph.D. in Bio-ethics Philosophy at the Kennedy Institute of Ethics at Georgetown University. An author of some 35 academic articles and book chapters and peer review literature, we welcome you here, Dr. Meslin and look forward to your testimony. As I say the clocks are set at five minutes to leave maximum time for questions and answers.

DR. ERIC MESLIN: Thank you very much, Senator and good morning, good morning to you Senator Harkin. I was privileged to appear before your subcommittee on December 2nd to offer some brief remarks on the subject of human stem cell research. And at that hearing, Mr. Chairman, I informed the subcommittee that in his November 20th letter to President Clinton the NBAC chair, Dr. Harold Shapiro (sp) addressed

only the immediate issue of the purported experiment involving the fusion of a cow egg and a human cell. And that NBAC would devote a majority of it's next meeting to the broader issues raised by President Clinton in his November 14th letter to the commission. Namely that NBAC undertake a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations.

Just this past week NBAC met for the 26th time since being established by President Clinton. The commission devoted the entire day, January 19th to the topic of human stem cell research, hearing testimony from a number of leading scientists, bio-ethicists, theologians, legal scholars and the public. The purpose of this meeting was to provide NBAC with a deeper understanding of the ethical, scientific, legal, medical, and policy issues that are raised by this important area of research.

While the commission did not reach any immediate conclusions at that meeting, nor where they expecting to, it may be helpful to describe the range of issues that were discussed, and then to describe our timetable for completing this report, since I understand how important it is to you. In our view, an understanding of the legal status regarding the use of federal funds to conduct human stem cell research provides an important context for fully understanding the ethical issues. At our recent meeting, we were very interested to learn that the office of the General Counsel has rendered an opinion regarding whether federal funds may be used for research conducted with human pluripotent stem cells.

We're planning to carefully review this opinion as quickly as possible, since it provides one of the many pieces of valuable information we will rely on to fully address the bio-ethical issues involved in this area of research. In testimony before us, Mr. Chairman, we heard some compelling arguments in favor permitting research on human stem cells, based principally on the very promising results of previous animal studies. Several beneficial uses of these cells are anticipated, and you've heard those from Dr. Varmus already.

It was also clear that a number of important scientific issues must be resolved before any actual therapies can be developed or tested in human beings. These include how to specifically direct stem cells to differentiate into specific types, such as cardiac muscle or nerve cells, how to overcome the problem of immune rejection of such transplanted tissue, and other items.

We also heard some words of caution and objection to all forms of research involving the human embryo, the human fetus, or the cells or tissues derived from these sources, respectively. Some of these concerns related to the potential for complicity in the use of cells derived from spare or excess embryos, other concerns related to more fundamental objections to the use of human fetal or embryonic material irrespective of their source or potential for benefit.

Mr. Chairman, the focus of the NBAC effort is to develop sound public policy proposals based on appropriate scientific, medical, ethical and legal considerations. In this respect we hope to use the experiences from a number of former deliberative bodies.

MORE

And as with all NBAC reports our deliberations, agendas, transcripts and working papers will be available on our Web site. In reviewing a working draft outline of the report prepared by my staff, the commission at its meeting, expressed a strong interest in developing a report that was focused on a set of answerable and timely questions, but that would also be able to anticipate certain issues.

The specific issues our report will address are now being developed for NBAC's consideration, but they will likely focus on some of the following points. Is there an ethically relevant distinction

between research using human stem cells derived from fetal material versus research using human stem cells obtained from existing embryos? How should considerations about the source of human stem cells be incorporated into the analysis? Is it ethically acceptable to produce new human embryos as a source of stem cells for research? And finally, what is the appropriate role of the federal government in overseeing research of this kind? NBAC would hope that one of the results of its deliberations on this topic would be to identify the bio-ethical issues that ought to be considered when supporting such research or developing guidelines for reviewing research in this area.

Now let me say a word about our timetable. As you know, Mr. Chairman, NBAC is subject to the Federal Advisory Committee Act, which you helped co-sponsor. This requires that we conduct all of our business in public and come to conclusions in public. This means that any Commission decisions, be they interim conclusions or final recommendations, can only occur at NBAC meetings. We are committed to completing this report by June of 1999 or thereabouts, so NBAC and its staff have mobilized to work as expeditiously as possible. Additional meetings have now been scheduled. In fact, we will be meeting next Tuesday and Wednesday, February 2nd and 3rd in Princeton, New Jersey and monthly thereafter.

I should note, however, that the commission is also preparing for the possibility of being able to provide to the President conclusions on certain issues within the next few months. We are keenly aware of NIH's interest in moving forward with human stem cell research and Dr. Shapiro has already indicated to Dr. Varmus separately that, if NBAC reaches any interim conclusions, they will be shared with NIH and others after they're transmitted to the President.

Naturally, Mr. Chairman, we'll be pleased to provide you and your staff with an update on our work as it proceeds. I'd be pleased to answer any questions you may have.

SEN. SPECTER: Thank you very much, Dr. Meslin.

But we now turn to Mr. Richard Doerflinger, associate director for policy development at the Secretariat for Pro-Life Activities National Conference of Catholic Bishops.

Welcome, Mr. Doerflinger. We appreciate your coming back and the floor is yours.

MR. RICHARD DOERFLINGER: Thank you, Mr. Chairman.

I want to begin by noting that a point I made in my December 2nd testimony on this same matter has received new support from recent events. Since then, two startling scientific breakthroughs have made it even more clear that destructive embryo research is unnecessary. Advances in the use of telomerase to promote regeneration of human tissues and the new discovery that adult stem cells may be far more versatile than was once thought offer the promise that embryonic stem cells may simply be irrelevant to future medical progress.

At the December 2nd hearing, Dr. Varmus noted that while adult stem cells can be obtained from bone marrow, cord blood and so on, they're of limited use compared to embryonic cells because they can not form other kinds of tissue, such as nerve and skin. The most recent issue of Science suggests that this judgement may well have been premature. That, in fact, stem cells at a later stage of development can cross over these boundaries and be adapted to perform the use of any different kind of cell.

This subcommittee has now held three hearings on one narrow avenue of research, precisely the avenue that raises the most obvious moral and legal problems. So far, to the exclusion of all other alternatives, even when those avenues may be more promising, the use of adult stem cells, for example, is said to promise the complete avoidance of the tissue rejection problems that Dr. Varmus has noted, still need to solved using embryonic cells.

I would urge the subcommittee to expand its vision to explore the alternatives that will advance medical progress and the well being of patients without demeaning human dignity.

Turning now to the legal memorandum prepared by the Department of Health and Human Services. In its effort to find that federal funding of embryonic stem cell research is consistent with congressional intent, HHS has overlooked some rather obvious facts and created its own arbitrary definition of a human embryo, and even more striking, of a human being that have no basis in biology or federal law.

First, looking at current laws on embryo and live fetal research, HHS now claims that current law and embryo research does not pose a barrier to embryonic stem cell research because the law protects only the embryo, which is an organism. And a stem cell obtained by destroying embryos is not an organism. HHS even cites me on this point, but they ignore other parts of my testimony and more importantly ignore two important aspects of current law.

First, as I noted on December 2nd., there is a factual uncertainty as to exactly what happens to the stem cells where Dr. Gearhart of John Hopkins University has cultured from fetal germ cells after abortions. After being cultured, some of these stem cells have a tendency to come back together and show signs of developing as an early embryo. Whether the formation of early embryos does take place in such a culture, and whether that can be prevented by adapting the research is a scientific question, can't be answered by attorneys.

A stem cell is not an organism, but the possibility must be explored that groups of stem cells may re-congregate in some of this research to form and entity that is, however briefly, a living organism, in which case this research could not be funded.

HHS seeks to avoid this factual inquiry by inventing its own narrower definition of an embryo, which is not found in federal law. Such an entity, HHS argues, cannot be an embryo, because even if implanted in a womb, it could not become a, quote, "Human being." Oddly enough, the key phrase human being is not defined, but from the context, it seems to refer to a live born infant. Doctor Varmus' testimony, I noted, he said a human being is a mature organism. So, I'm beginning to wonder whether my six year old son qualifies.

Embryology textbooks, however, tell us that in biological terms, the embryo is a human being. And the current federal law treats the embryo as a human subject, since 1975, has treated the human embryo as a human subject to be protected from harmful research, from implantation onwards, and the current embryo research writer is intended that protection back before implantation, to the embryo in the laboratory.

Secondly, HHS seems to misread the embryo research writer itself rather obviously, by saying that this research can be funded as long as federal funds are not used for the actual destruction of the embryo. It can be used for all subsequent work with the stem cells so derived. But Congress knows how to write a writer that says you simply can't use federal funds for that act, it wrote the writer that way, when it dealt with creation of human embryos. It said federal funds cannot be used for creation of embryos. Then it said, federal funds cannot be used for research in which a human embryo or embryos are destroyed or discarded or subjected to risk of harm. Obviously, that means if this is an integral part of the research protocol, even if it's not directly funded by federal funds, the destructive harvesting of embryos is not supposed to be something that is part of the research project funded by Congress.

Finally, HHS ignores the possibility that the fetal tissue transplantation guidelines now in law apply also to the destruction of embryos in the laboratory. The statute clearly says that it covers tissue derived from embryos or fetuses and it only allowed the use of that tissue if the subject was dead before the tissue was obtained and only if the destruction was not altered in its method or timing by the needs of the research. Well in all of the research in which embryos are destroyed here, the destructive process is geared exactly toward obtaining usable research tissue and toward nothing else. When embryos are discarded in an IVF clinic, they don't use immuno-surgery

out
2/26/99

to dissect the inner cell mass from the trophoblast, they simply throw them away. Everything about the harvesting procedure is altered to obtain usable tissue and it is the harvesting procedure that is, itself, the abortion or the destruction.

In conclusion, if Congress wishes to insulate its funding of medical advances from the destruction of innocent life, there's a very simple way to do just that. It should devote its funds to stem cell techniques and other promising avenues of research that in no way depend upon such destruction and that way our government will truly serve all the people by showing that it will not promote the destruction of one human being to serve another or the development of treatments that millions of Americans would find it morally abhorrent to use.

Thank you.

SEN. SPECTER: Thank you, Mr. Doerflinger.

Dr. Rabb, the opinion, which you have rendered, focuses on the proposition that while cells are units of organisms, organisms are units of life. Except for unicellular life, a cell does not equal an organism, which is recognized as an animal or plant, not a collection of uni-cells but a multi-cellular cooperative with the emergent properties of the whole organism. Now in that context how would you respond to what Mr. Doerflinger has said, that stem cells may re-cogenerate into what could be a whole organism. Is that a possibility?

DR. RABB: I can't respond on the science, Senator Specter. The question that was asked of me was whether, if one were dealing with an entity that was not an organism, would one violate the human embryo ban? And the answer to that is, no, one would not violate the ban, if one were doing research with an entity that was not an organism.

If the question is, whether one can research with an organism that would otherwise be subject the human embryo ban, the answer then again would be, no, one couldn't do such research. But the science was not in my domain. The law was. And we didn't create our own definition of an embryo. The definition that we used was the one in the statute.

And as Senator Harkin point out at the last hearing, at which Dr Varmus appeared, the statute defines human embryo in terms of an organism. And that was the question from my office, and the answer we found through science was that these stem cells, not being organisms, are not subject to the ban.

SEN. SPECTER: So, when Mr. Doerflinger says that the destructive harvesting of embryos is indispensable, would your response be that stem cells can be obtained for this kind of research without the destructive harvesting of embryos?

DR. RABB: That's a science question again, Senator Specter. What I can say is that however derived, not using federal funds, once derived, stem cells are not organisms and therefore are not subject to the ban.

SEN. SPECTER: Well, since it's a science question, Dr. Varmus you enter center stage here. Is it possible to acquire these stem cells for the research without having the destructive harvesting of embryos?

DR. VARMUS: At this point, Senator, no. The cells derived from embryos do require the destruction of the embryo. Obviously, in derivation from fetal tissue, the tissue comes from a fetus, which is already died. Let me make a point about the issue that Mr. Doerflinger raised with respect to whether pluripotent stem cells ~~and~~ in culture can become organisms. It's true that sometimes these cells can aggregate and may appear like one of the early phases in the development of a normal embryo. But to my mind, nothing would be less ethical than to attempt to ascertain whether or not this was indeed the precursor to an organism, a viable embryo. That, that would require returning that mass of cells to a uterus to ask whether it has the potential development to develop into a fetus and then a newborn

and the prospect for developing a severely impaired individual would be enormous and to my mind reprehensible means of doing research.

SEN. SPECTER: Dr. Rabb, you made a comment that except for the unicellular life a cell does not equal an organism. Would you explain what you mean by the exception of the unicellular life?

DR. RABB: I'm going to try. This gets to be science again. An organism is as it's been explained to the science is an individual instituted to carryout all of life functions. There are some unicellular animals. For those animals, the full potential of their lives inheres in a single cell. For human beings it is the complex interrelationship of all of the human systems that make up the organism. And --

SEN. SPECTER: Dr. Varmus, one final question for you. When Mr. Doerflinger makes the point that we have ignored other new developments, which might lead us to the same avenues as stem cells, are you pursuing the kinds of lines of inquiry that Mr. Doerflinger suggests --

DR. VARMUS: Absolutely, Senator. I'm glad you brought that up. Many of us were pleasantly surprised by the report that appeared in Science this week, a copy of which I have given your staff, that shows that stem cells taken from the mouse brain, grown in culture, can be returned to a mouse and produce blood cells. This indicates a level plasticity that was unexpected and, of course, a very promising area of research.

But I must emphasize, this is one report carried out in one way with one strain of mice. But if this approach will be applicable in other strains of mice, other animals with other types of cells, whether we can identify what is responsible for reprogramming the cell, all matters of conjecture. My view is, yes, we should be pursuing this and many other lines of investigation with relation to many kinds of stem cells. But to say that we should put our eggs in one basket and not in all the available baskets would be a serious mistake.

SEN. SPECTER: So, you're saying that NIH has eggs in those other baskets?

DR. VARMUS: Absolutely.

SEN. SPECTER: Senator Harkin.

SEN. HARKIN: Thank you, Mr. Chairman.

Mr. Doerflinger, I was just reading an article that you had written here for the National Right to Life News, which I found interesting. Let me just ask you, in vitro fertilization is not illegal, is it?

MR. DOERFLINGER: No.

SEN. HARKIN: Is it immoral?

MR. DOERFLINGER: In Catholic teaching, there are immoral problems with it, yes.

There's a good bit of research however involving in vitro fertilized embryos that is illegal in various states.

SEN. HARKIN: I don't think the church has taken the position that an infertile couple can engage in, in vitro fertilization. Maybe I'm wrong --

MR. DOERFLINGER: The catholic teaching does not accept in vitro fertilization as a solution for infertile couples. It urges them to pursue fertility treatments that will help their sexual union to be pro-creative, if that's what they want rather than to substitute a laboratory procedure for that.

SEN. HARKIN: Well, I'll have to check, but I didn't think that they'd taken an absolute position against in vitro fertilization.

So, you have in vitro fertilization --

MR. DOERFLINGER: I'm pretty close to that situation, Senator.

SEN. HARKIN: Huh?

MR. DOERFLINGER: Working for the National Conference of Catholic Bishops, I'm fairly close to that situation.

SEN. HARKIN: Well, I'm sure you would be. I would hope so.

(Laughter.)

But, I still, I didn't think that they had taken a position that said that you can't use in vitro fertilization, but maybe I'm wrong. I don't know.

MR. DOERFLINGER: I'll be glad to send you the documents on it.

SEN. HARKIN: Am I wrong?

MR. DOERFLINGER: Uh --

SEN. HARKIN: Have they taken an absolute position on it?

MR. DOERFLINGER: I never like to say that up front to a Senator, but I think so Senator. I'll send you the documents on it.

SEN. HARKIN: Well, I don't know, I mean you're the authority on that, I don't know. And -- send it to me.

MR. DOERFLINGER: Among the concerns that have been raised beyond the Catholic Church about the procedure is the prospect for abuses to the embryos that come out of the procedure, the culling of high quality embryos, the discarding of embryos --

SEN. HARKIN: Well, that's my point --

MR. DOERFLINGER: The selective reductions that are proposed when too many of the embryos implant and these are all part of the problem.

SEN. HARKIN: So, we've got in vitro fertilization, at least it's not illegal, we have a lot of it going on and obviously, there are a lot of leftovers that are frozen. What happens to them?

MR. DOERFLINGER: Some are frozen indefinitely. Some are ultimately used for later attempts at having a child. And some are experimented on and some are thrown away, some are destroyed.

SEN. HARKIN: Well if, in fact, this is not illegal and they are, in fact, some are destroyed, why not use them to get the pluripotent cells that we need to do the kind of research that may help us in the future alleviate human suffering? I don't understand why we can't do that.

DR. DOERFLINGER: Well, Senator, I think that's a question that we explored a little bit at the last hearing. There are lots of things that go on in the private sector that are going to go on anyway that Congress has decided not to add its encouragement to by giving federal funds, abortion being an excellent example. It's not only legal, I mean it's more legal than destructive embryo research, which is a felony in several states. It's defined as a constitutional right, but Congress has decided we're not going to use federal funds to give our endorsement to it.

I think you could just as well say if you're walking down the street and you find a bunch of big tough guys beating up an old man, a question arises whether, before they're done with him, you could take his liver because you need it, and thus killing him a little earlier. I don't think whatever somebody else is doing out there in the private sector that they're going to do anyway has much influence in what Congress has to decide in its policy decision on what to promote. See in this case, this is not a case analogous to the fetal tissue situation where the abortion's been done. And as Henry Waxman said in 1993 on the House floor, the only question left is whether to throw away the tissue that's left after the fetus is dead, or make use of it. Here is a case where the researcher's harvesting procedure does the destruction itself. That's a very different moral proposition.

SEN. HARKIN: But it's going to take place, as I said.

DR. DOERFLINGER: It's going to take place anyway. Senator you and every other Senator in the Senate voted in 1997 to reject federal funding of euthanasia, even though all of those people are going to die pretty soon anyway.

But it makes a difference whether they're going to die of some other cause or whether the government's going to help kill them.

SEN. HARKIN: Well, as you said, here, in this article, you said that, such experiments that we're talking about here create new human life. I thought we got through that. Organisms, these are not organisms. They can not develop into full human life. That every scientist I've ever asked that question to says that and yet, you seem to want to bring it back across that boundary line again and I just

don't understand that.

MR. DOERFLINGER: Well, I think what I was saying, Senator, was there is a factual uncertainty about one of these experiments, Dr. Gearhart's, which is, you know, it can be settled in a factual way. It's an uncertainty he, himself, has and the question, the answer that Dr. Varmus has given is intriguing because if we really don't know and there's no ethical way to find out, that might answer the question in the direction of saying, we can't fund it, then.

But my broader question was simply that HHS gave an answer to that question, which is probably right as far as it goes, but it's the wrong question because the embryo research writer was not intended only to say that you can't use federal funds for the destructive act itself. It was designed to prevent federal funding of an entire research project in which these are destroyed, even if they're destroyed with private funds.

SEN. HARKIN: Well, I disagree with that interpretation. I adamantly disagree. That's maybe your interpretation. I don't believe Congress -- you have to show me report language or anything else that indicates that we intended it to be that broad and that encompassing. I don't believe that.

MR. DOERFLINGER: We have two clauses there right next to each other. The first one says, you can't use federal funds for creation of embryos. If your interpretation is right, I can't think of a blessed reason why they didn't just say, federal funds can't be used for destroying embryos. They didn't say that. Instead, they said, they used an entirely different phrase right next to the first one saying, can't be used for research in which embryos are destroyed or discarded. Now, that can't mean the same thing as the first clause cause it's very deliberately written more broadly.

SEN. HARKIN: I have to think. You lost me on that one. I have to --

MR. DOERFLINGER: If you want to rewrite the writer, then we can have a debate about that.

SEN. HARKIN: Here it is. This is it right here.

None of the funds made available by PL 10491 may be used for one, the creation of a human embryo or embryos for research purposes.

Two; research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR, et cetera.

For the purposes of this section, I will read one more time.

The phrase human embryo or embryos shall include any organism not protected as a human subject under 45 CFR 46 as of enactment of this act, et cetera, et cetera, et cetera.

Now again, I think that's the essence of the finding at HHS. It is clear that these are not organisms --

MR. DOERFLINGER: -- That the stem cells are not organisms.

SEN. HARKIN: -- and research cannot be covered by that law, Mr. Doerflinger.

If you want to change the law --

MR. DOERFLINGER: I'm not talking about the stem cell being an embryo, I'm talking about the stem cell that you have to kill to get the stem cells.

SEN. HARKIN: Wait a minute.

MR. DOERFLINGER: As an integral part of that is critical.

(Cross talk)

SEN. HARKIN: -- to get the stem cell. I don't understand what you just said.

You said, the stem cell you have to kill to get the stem cell.

MR. DOERFLINGER: No, I said the embryo you have to kill to get the stem cells.

The stem cells are simply the inner cell mass of an embryo. The way the stem cells is obtained is by doing microsurgery on an embryo and sucking out the inner cell mass to provide stem cells for culture. What I'm saying is the destruction of that initial embryo in two of

the three experiments we're talking about because Dr. Gearhart's experiment is using fetal tissue. But in Dr. West and Dr. Thompson's experiments, integral part of the research protocol is you must arrange for these embryos to be destroyed by the harvesting of these cells. It is not after the embryo is dead. It is what kills the embryo.

It seems to me that that's what Congress was intending to prevent.

SEN. SPECTER: Senator Harkin do you have another question?

SEN. HARKIN: No thank you very much, Mr. Chairman.

SEN. SPECTER: Thank you very much.

Senator Hollings.

SEN. HOLLINGS: Would you care to comment on -- (off mike.) -- ?

DR.VARMUS: I think the point is that the law for our minds reads quite clearly. And it's not our job to try to discern intent when intent is not described by report language or other means of discernment. So, our view is that there is a very clear distinction to be made between research in which stem cells have been developed in one laboratory by one procedure are then used by other investigators to support other kinds of research. That is not research in which an embryo, an organism is subjected to risk from those that are dictated by other statutes.

SEN. HOLLINGS: Thank you, Mr. Varmus.

SEN. SPECTER: Thank you, Senator Hollings.

We are now slightly past 10:00, so we're going to have to adjourn. We thank you very much for coming again today. And this is obviously going to be an ongoing matter of great public interests as we pursue the steps, which are set up. And we appreciate your participation Mr. Doerflinger to give us your analysis. And you have immunity here when you criticize Senators. You can say Senators are wrong. That comes under --Senator Hollings is accurate about that, but you have a privilege to make those statements. We're here to have an exchange and we appreciate your incisiveness, and your study, and your knowledge in the field. And we thank you Dr. Varmus, Dr. Rabb, and Dr. Meslin and stay tuned. Thank you all very much.

End of hearing.

END

.ETX

Report is Completed